REMARKS

Claims 1-6, 8-15, and 23-27 are pending in the application. By this amendment, claims 1, 2, 4, and 10 have been amended, claims 24-27 have been added, and claims 7, 17, 18, 20, and 21 have been canceled. Claim 1 d) has been amended to recite an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO:5, said fragment consisting of at least 40 contiguous amino acid residues of SEQ ID NO:5. Support for this amendment can be found in the specification at page 10, lines 4-15 and in Example XII at page 51. Support for new claims 24-27 can be found in the specification, for example, at page 7, lines 16-18, page 15, lines 25-27, page 38, lines 17-23, page 40, lines 2-10, page 41, lines 1-11, and Example VII at page 48. No new matter is added by the amendments to the claims or the addition of the new claims. Claims 16, 19, and 22 were intended to be cancelled previously as stated in Item 13 of the Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing under 35 U.S.C. 371). Applicants again request the cancellation of these claims. Applicants submit that these claims were included in the application as filed in the interest of providing notice to the public of certain specific subject matter intended to be claimed, and were intended to be canceled at the time of filing this application in the interest of reducing filing costs. Applicants expressly state that these claims are **not** being canceled for reasons related to patentability, and are in fact fully supported by the specification as filed. It is noted that, while Applicants have canceled and not repeated new versions of the claims of Group III, drawn to a transgenic organism and Group V, drawn to agonists and antagonists. Applicants expressly assert that these claims have been canceled for reasons relating to cost and efficiency of prosecution of the presently elected claims, and not for reasons relating to patentability. Applicants further expressly reserve the right to pursue the subject matter of canceled claims, or any other subject matter disclosed but not herein claimed, in a later continuation or divisional application.

I. Amendment to the Specification

The specification has been amended to add the priority information necessary to comply with 35 U.S.C. § 119(e) and 37 C.F.R. § 1.78. Applicants previously made a proper claim to

priority under Article 8 of the Patent Cooperation Treaty (See pages 1-2 of the Declaration and Power of Attorney filed March 22, 2002).

II. Comments Regarding Restriction Requirement

Applicants hereby elect, with traverse, to prosecute Group II, which corresponds to claims 3-6, 10, and 11, and, in addition, elect the polynucleotide sequence of SEQ ID NO:10.

A. The unity of invention standard *must* be applied in national stage applications

Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides:

> ... [W]hen the Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111....
>
> In applying PCT Rule 13.2 to ... national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2....

Id at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable ... in national stage (filed under 35 U.S.C. 371) applications.

Id at page 1800-149, column 1.

B. Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the MPEP strongly support a finding of unity of invention among all of the claims in the present case

1. Unity of Invention is accepted between claims to polypeptides and claims to the polynucleotides which encode them

Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT provides that unity of invention is accepted between a protein and the polynucleotide that encodes it:

> *Example 17*
> Claim 1: Protein X.
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicants submit that claims drawn to the polypeptide sequence of SEQ ID NO:5 (*i.e.*, claims 1, 2, and 15 of Group I) and claims drawn to the elected polynucleotide sequence of SEQ ID NO:10, which encodes SEQ ID NO:5 (*i.e.*, claims 3-6, 10, and 11 of Group II), meet the unity of invention requirements.

2. Unity of invention exists with respect to dependent claims in the same claim category as the independent claim from which they depend

MPEP section 1850(A) and 1893.03(d), which recite the provisions of paragraph (c) of Part 1 (entitled "Instructions Concerning Unity of Invention") of Annex B (entitled "Unity of Invention") to the Administrative Instructions Under the PCT, provides:

> **(A) Independent and Dependent Claims.**
>
> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).

> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, **it does not matter if a dependent claim itself contains a further invention**.... (Emphasis added.)

See MPEP section 1850(A) at page 1800-61. See also MPEP Appendix AI at page 53.

Accordingly, claim 9, drawn to antibodies, should also be examined together with claim 1, drawn to the polypeptides from which claim 9 depends. Moreover, claims 2, 3, 9, and 15, all of which depend from claim 1, are all directed to compositions of matter, *i.e.*, to products. Further, as discussed above, there is unity of invention among claims 1 and 3.

3. Unity of invention exists among all of Applicants' claims

MPEP 1850 provides:

> Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. The determination is made based on the contents of the claims as interpreted in light of the description and drawings. Annex B also contains examples concerning unity of invention.

Id at page 800-61.

MPEP 1893.03(d) similarly provides:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

Id at page 1800-149.

In the present case, unity of invention exists among all of Applicants' claims. The sequences of the claimed polypeptides and the sequences of the claimed polynucleotides encoding those polypeptides are corresponding technical features which are common to all of Applicants claims, which serve to technically interrelate all of Applicants' claims, and which

define the contribution over the prior art made by each of them. Thus, Applicants' claims are linked to form a single general inventive concept, and Applicants are therefore entitled to prosecute all of their pending claims in a single national stage application.

4. The sequences of the claimed polypeptides and the claimed polynucleotides encoding those polypeptides, are corresponding technical features that are common to all of Applicants' claims and that serve to technically interrelate them

The sequences of the claimed polypeptides and corresponding polynucleotides are common to all of Applicants' claims, given that each claim refers to one or both either explicitly or implicitly, by virtue of depending from a claim which makes an explicit reference to the sequences of the claimed polypeptides or claimed polynucleotides.

Moreover, the sequences of the claimed polypeptides and corresponding polynucleotides serve to technically interrelate all of Applicants' claims. Applicants' composition of matter claims 1-6, 9-11, and 15) are drawn to either the polypeptides or polynucleotides themselves (1 and 2, drawn to polypeptides, and 3-6, 10, and 11, drawn to polynucleotides), to compositions of matter which comprise the polypeptides or polynucleotides as one element (5 and 6, drawn to recombinant polynucleotides and transformed cells, respectively, and 15, drawn to pharmaceutical compositions), or to compositions of matter wherein the sequences of the claimed polypeptides functionally limit the claimed subject matter (Claim 9, drawn to an antibody which specifically binds a polypeptide of claim 1).

In Applicants' method claims 8, 12-14, 23, 26, and 27), the claimed polypeptides or polynucleotides serve as either the product of the claimed method (claim 8, drawn to a method of polypeptide production) and/or as a reagent for performing the method (claims 12 and 26, drawn to methods of detecting a target polynucleotide in a sample; claim 23, drawn to a method of screening a compound for effectiveness in altering expression of a polynucleotide of claim 4; and claim 27, drawn to a method of assessing toxicity of a test compound using a polynucleotide of claim 10).

Therefore, the sequences of the claimed polypeptides and polynucleotides are corresponding technical features which are common to all of Applicants' claims, and which serve to technically interrelate them.

5. Minimal burden to search claims 12-14, and 23-27, under U.S. practice

Applicants also respectfully submit that the search required to identify prior art relevant to the polynucleotides of Group II should substantially overlap with that required for examination of claims 12-14 (GroupVI), claim 23 (Group V) and newly added claims 26 and 27, which are drawn to methods of using the elected polynucleotides, and newly added claims 24 and 25, which are drawn to microarrays using the elected polynucleotides.

III. Rejoinder of method claims upon allowance of product claims under U.S. practice

The Examiner is reminded that claim 8 (Group I), claims 12-14 (Group VI), claim 23 (Group V) and newly added claims 26 and 27, drawn to methods of using the elected polynucleotides of Group II should be rejoined per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," which sets forth the rules that upon allowance of any of the product claims, the method claims covering the same scope of products be rejoined. Applicants request that claim 8 (Group I), claims 12-14 (Group VI), claim 23 (Group V) and newly added claims 26 and 27 be rejoined and examined upon allowance of any claim drawn to the claimed polynucleotides.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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